

Claims

1. A method for detecting the presence of malignant cancer in a subject comprising:

comparing *KAI1* gene sequence, *KAI1* mRNA or *KAI1* protein of said subject to wild-type *KAI1* gene sequence, mRNA or protein, an observed alteration in *KAI1* gene sequence, *KAI1* mRNA, or *KAI1* protein of said subject as compared to wild-type indicating the presence of malignant cancer in said subject.

2. The method of claim 1, wherein *KAI1* gene sequences are compared.

3. The method of Claim 2 wherein said alteration in *KAI1* gene sequence is detected by Southern hybridization.

4. The method of Claim 2, wherein said alteration in *KAI1* gene sequence is detected by cloning *KAI1* genes of said subject and sequencing all or part of the cloned gene.

5. The method of claim 2, wherein said alteration in *KAI1* gene sequence is detected by PCR-SSCP.

6. The method of claim 5, wherein the primers used in said PCR step are derived from *KAI1* cDNA.

7. The method of claim 5, wherein the primers used in said PCR-SSCP are selected from SEQ ID NOS:1-12.

8. The method of claim 1 wherein *KAI1* mRNA molecules are compared.

9. The method of claim 8, wherein said alteration in *KAI1* mRNA is detected by Northern blotting.

10. The method of claim 8, wherein said alteration in *KAI1* mRNA is detected by RT-PCR.

11. The method of claim 10, wherein the primers used in said PCR step are derived from *KAI1* cDNA.

12. The method of claim 8, wherein said alteration in *KAI1* mRNA is detected by RT-PCR-SSCP.

13. The method of claim 12, wherein the primers used in said PCR step are derived from *KAI1* cDNA.

14. The method of claim 1, wherein *KAI1* proteins are compared.

15. The method of claim 14, wherein said alteration in *KAI1* protein is detected by Western blotting.

16. The method of claim 15, wherein said alteration in *KAI1* protein is detected by immunohistochemistry.

17. Antibodies having specific binding affinity for *KAI1* protein or peptide fragments thereof.

18. The antibodies of claim 17, wherein said antibodies are monoclonal antibodies.

19. Purified and isolated primers having nucleic acid sequences selected from the group consisting of SEQ ID NOs: 1-12.

20. A diagnostic kit for use in detecting the presence of malignant cancer in a subject, said kit comprising:

° primers having nucleic acid sequences selected
from the group consisting of SEQ ID NOs: 1-12.

21. A gene therapy method for a subject having
altered *KAI1* expression comprising administering to said
5 subject a recombinant expression vector having a nucleic
acid sequence capable of directing host organism synthesis
of wild-type *KAI1* protein.

10

15

20

25

30

35